3/3 #11

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Dane K. FISHER *et al.*		Art Unit:	1655
Appln. No.:	09/619,643	Examiner:	J. Goldberg
Filed:	July 19, 2000	Atty. Docket:	38-21(51230)B
For:	Nucleic Acid Molecules and Other Molecules Associated with Plants		

APPELLANTS' BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on December 6, 2001. The statutory fee of $320.00 for submitting this Brief is included in our attached Check No. 150799. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167. Monsanto Company is a subsidiary of Pharmacia Corporation, located at 100 Route 206 North, Peapack, New Jersey 07977.

2. Related Appeals and Interferences

The Appellants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claim 1 is pending. Claims 2-7 have been cancelled without prejudice. Claim 1 is independent. Claim 1 stands finally rejected under 35 U.S.C. §§ 101, 102, and 112, first paragraph. Appellants appeal all of the rejections of claim 1.

4. Status of Amendments

Applicants have not filed any responses subsequent to Final Rejection in this case.

5. Summary of Invention

The invention is directed to nucleic acid molecules that encode maize proteins or fragments thereof. The claimed nucleic acid molecules were derived from a cDNA collection prepared from maize pooled leaf tissue. Specification at page 30, lines 21-24 and page 79 line 17 through page 80 line 7. More particularly, the present invention is directed to: a substantially purified nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.

6. Issues

The issues in this Appeal are:

(a) whether claim 1 is unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claim 1 is unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility;

(c) whether claim 1 is unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description; and

(d) whether claim 1 is unpatentable under 35 U.S.C. § 102 for alleged anticipation.

7. Grouping of Claims

Independent claim 1 remains in this case. As no other claims are pending, claim 1 does not stand or fall with any other claims. A copy of the claim on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Appellants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example the ability to identify the presence or absence of a polymorphism in a population of maize plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acids provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acids that demonstrates Applicants' possession of the claimed invention. Each genus of claimed nucleic acid molecules, *i.e.*, the five genera of nucleic acid molecules comprising the nucleic acid sequences of SEQ ID NO. 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5, has been described by the recitation of a common structural feature – the nucleotide sequences of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5, respectively – which distinguishes molecules in the genus from molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of (and have provided an adequate

description of) the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

The claim was erroneously rejected as anticipated by two references which fail to teach any of the recited nucleic acid sequences. The Examiner improperly considered non-identical chemical compounds to anticipate recited SEQ ID NO: 5, despite the fact that the chemical compounds fail to teach the chemical composition of SEQ ID NO: 5. Moreover, the Examiner based his rejections for anticipation not on what exists in the art or what the art teaches. Instead, the rejections are based on the Examiner's theory, unsupported by any evidence, that the prior art could have taught the recited nucleic acids if either the prior art nucleic acids or the recited nucleic acids were improperly sequenced. Such clearly unsupported conjecture is simply not a proper basis for an anticipation rejection.

B. The Claimed Nucleic Acids Have Legal Utility

Pending claim 1 was erroneously rejected under 35 U.S.C. § 101 because the claimed invention was allegedly not supported by either a "substantial utility" or a "specific asserted utility." Final Action mailed September 6, 2001 (Paper No. 9) ("Final Action") at pages 4-5. According to the Final Action, the "claimed nucleic acids do not have a substantial or specific utility. Each of the provided utilities is general." Final Action at page 8.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson.* The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir.

1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example use to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling. Either of these utilities alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and they have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

Applicants have asserted that the claimed nucleic acid molecules[1] are themselves useful for utilities disclosed in the specification, *e.g.*, to detect the presence or absence of

[1] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

polymorphisms, and as hybridization probes for expression profiling. The specification also discloses additional utilities for the claimed nucleic acid molecules, including introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to screen for compounds such as a herbicide. Specification at page 73, line 17 through page 74, line 17. For example, a compound can be provided to both an antisense plant and a control plant (no antisense) and the effect of the compound on the plant can be monitored. Such a screen is analogous to a cell-based assay, which has a legally sufficient utility.[2] Thus, the use in such a screen of a plant or plant cell having an introduced claimed nucleic acid molecule is a legally sufficient utility. Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[3] and use as molecular markers.[4]

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 35, line 20 through page 42, line 6. The Examiner argues that this utility, like all of the asserted utilities,

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[2] *See, e.g.*, MPEP § 2107 at page 2100-25.

[3] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, drought stress. Contrary to the Examiner's assertions, this use is not using the claimed nucleic acid molecules to identify a "'real world' context of use." Final Action at page 6. It is a **use** of the claimed nucleic acid molecules in a real world context.

[4] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

is not specific or substantial, *see* Final Action at page 5, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility.

Many of the disclosed utilities in this case, including this utility, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates this utility by asserting that these uses are not "useful" because a scientist would not know how to use the information gathered or the nucleic acid molecule being measured. *See* Final Action at page 7. However, the fact that, for example, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-25.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[5] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

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[5] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit – to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal utilities because the specification has not disclosed any specific nucleic acid molecule that can be identified using the claimed nucleic acid molecules. Final Action at pages 7-8. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, *Arabidopsis*, barley, cotton, oat, oilseed rape, rice, etc.[6] Specification at page 27, lines 3-17. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and so has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using the claimed nucleic acid molecules is the promoter of the gene corresponding to the claimed nucleic acid molecules. Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 33, line 17 through page 34, line 8. The Final

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[6] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

Action denigrates that utility when it asserts that it is a utility that is applicable to nucleic acids in general. Final Action at pages 4-5.

In short, the Final Action appears to be arguing that the utility is not a legal utility simply because other molecules can be used for the same purpose, *i.e.*, chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acids. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter that is active in leaves at the time of anthesis. Isolation of such a promoter would be desirable and particularly useful because it allows expression of proteins at that important developmental state, including proteins that provide disease resistance. Because the claimed nucleic acid molecules were isolated from leaves, they provide an appropriate starting point for isolating a promoter active in leaves. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet

the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

It appears that the Final Action is arguing that the disclosed uses are legally insufficient or "insubstantial" under 35 U.S.C. § 101, but such an argument has no basis in law. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[7]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, for example, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a

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[7] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *See, e.g., In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Compare Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 706.03(a)(1). Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[8]

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[8] Examples of incredible utilities are given in MPEP § 2107 at page 2100-26, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on

A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a)(1).

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated August 15, 2001 at page 4, lines 1 through 10. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claim 1 was erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 8-9. This rejection has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer*

"flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

Co., 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides An Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that the specification teaches the "nucleic acids of SEQ ID NOs: 1-5", the adequacy of the written description has been challenged by the Examiner because the nucleic acid molecules of claim 1 are allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 9. The bases for the Examiner's challenge are that (1) one of skill in the art would allegedly conclude that Applicants were not in possession of the claimed nucleic acid molecules, and (2) there is allegedly "no adequate description of the genus of nucleic acids comprising SEQ ID NO: 1-5." Final Action at pages 9-10. These are not proper bases for a written description rejection of a "comprising" claim. If they were, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498,

1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, understand that Applicants had possession of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5, and therefore, the claimed invention.

Applicants have provided the nucleotide sequences required by the claims, *i.e.*, SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5, and have thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.[9] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence required by the claims (SEQ ID NOs: 1 through 5), for example, it describes vectors comprising the claimed nucleic acid molecules (specification at page 57, line 16 through page 64, line 23), and describes how to make the nucleotide sequences and the libraries from which they were originally purified.

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[9] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

See specification at page 1, line 11 through page 4, line 20, and Example 1. Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequences (SEQ ID NOs: 1 through 5) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[10] in particular at page 16, lines 9-13 (describing sequences with labels to facilitate detection), page 26, line 23 through page 27, line 17 (describing fusion nucleic acid molecules), page 3, lines 17-25 (describing automated nucleic acid synthesizers that can be used to build nucleic acid molecules), and page 75, lines 15-22 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

(2) Applicants Have Described the Claimed Invention

The Examiner asserts that because Applicants have "not disclosed any genomic DNA sequences and particularly has not disclosed any intron sequences or regulatory sequences....Applicants have not adequately disclosed the relevant identifying characteristics" of the claimed genus. Final Action at pages 11-12. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be "described by their complete structure." Final Action at page 11. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

The claimed nucleic acid molecules are actually five genera of nucleic acid molecules, each genus having a common structural feature of a particular enumerated nucleotide sequence,

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[10] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

i.e., SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, or SEQ ID NO: 5. The respective common structural feature (the nucleotide sequence) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not.[11] One skilled in the art would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, claim 1 satisfies the written description requirement of 35 U.S.C. § 112, and the rejection should be reversed.

E. The Claimed Nucleic Acid Molecules Are Novel

The Examiner has challenged the novelty of the claimed nucleic acid molecules in the Final Action. Claim 1 was erroneously rejected under 35 U.S.C. § 102(a), for allegedly being anticipated by Walbot (Genbank accession no. AI978199) ("Walbot 1") and by Walbot (Genbank accession no. AI734448) ("Walbot 2"). Final Action at pages 12-16.

Neither reference anticipates the present claims. For a prior art reference to anticipate in terms of 35 U.S.C. §102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q. 2d 1315, 1317 (Fed. Cir. 1988). *See also Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed.

[11] The same argument applies to each of the other genera, for example, if a fusion construct contains the nucleotide sequence of SEQ ID NO: 4, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 4.

Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). Neither Walbot 1 nor Walbot 2 teach every element of the claimed invention.

Although Walbot 1 and Walbot 2 are cited for the proposition that they anticipate claim 1 as directed to SEQ ID NO: 5, the Examiner admits that the Walbot references do **not** disclose the sequence of SEQ ID NO: 5. Final Action at pages 12 and 14. In fact, the sequence of Walbot 1 "differs from instant SEQ ID NO: 5 at a single position," *i.e.*, nucleotide 63, and the sequence of Walbot 2 "differs from instant SEQ ID NO: 5 at two positions," *i.e.*, nucleotides 35 and 63. Final Action at pages 12 and 14. Because the chemicals disclosed in the Walbot references are not the same as the chemical disclosed as SEQ ID NO: 5, every element of the claimed invention has not been identically shown in either of the references. *See Diversitech Corp.*, 850 F.2d at 677, 7 U.S.P.Q.2d at 1317. Accordingly, the Walbot references do not anticipate claim 1.

However, the Examiner contends that Walbot 1 and Walbot 2 *inherently* anticipate claim 1, and asserts:

> [t]he nucleotide sequence is an inherent property of the nucleic acid and is only one means by which a nucleic acid may be characterized. Thus, if an error in sequencing has occurred, the nucleic acids of the instant application and Walbot are inherently the same.

Final Action at pages 12-13, and 14-15. This assertion is incorrect.

"[T]o establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is ***necessarily*** present in the thing described in the reference." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). It is clear in this case that the nucleotide sequence of SEQ ID NO: 5 is not actually or ***necessarily*** present in the nucleic acid sequence disclosed in either Walbot reference. "The mere fact that a certain thing ***may*** result from a given set of circumstances [*e.g.*, sequencing errors] is not sufficient" to prove inherency. *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1951

(Fed. Cir. 1999) (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981)) (emphasis added).

No evidence, extrinsic or otherwise, has been presented by the Examiner in support of the proposition that sequencing errors are necessarily present in the nucleic acid sequences disclosed in either Walbot reference. Although the Final Action states that "'[a]ll extrinsic evidence' does in fact suggest that the nucleic acid taught in the prior art is identical to the claimed nucleic acid," no extrinsic evidence has been provided. Final Action at pages 13 and 15. Instead of providing evidence, the Examiner attempts to shift the burden of proof to Applicants to provide "evidence to substantiate the argument that the nucleic acids are not identical." Final Action at pages 14 and 16. This is not the law. Even if it were, as the Examiner has already admitted that the nucleic acids disclosed in the Walbot references are **not** identical to SEQ ID NO: 5 (*see* Final Action at pages 12 and 14), any requirement to prove non-identity would seem to be moot.

Neither Walbot 1 or Walbot 2 expressly anticipate claim 1 because neither reference teaches SEQ ID NO: 5 or any of the other claimed nucleic acid molecules. Further, neither of the Walbot references inherently anticipates claim 1 because no evidence has been provided in support of the Examiner's proposition that the missing nucleotides are necessarily present in the Walbot sequences. As such, claim 1 of the present invention is not expressly or inherently anticipated by Walbot 1 or Walbot 2, and the rejections must be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: February 5, 2002

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APPENDIX A

1. A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.

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February 5, 2002

Commissioner for Patents
Washington, DC 20231

Art Unit: 1655
Examiner: J. Goldberg

Re: U.S. Patent Application Serial No. 09/619,643
Filed: July 19, 2000
Inventors: Dane K. FISHER *et al.*
Title: Nucleic Acid Molecules and Other Molecules Associated with Plants
Atty. Docket: 38-21(51230)B (16517.001)

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appellants' Brief and accompanying Appendix A (in triplicate);
2. Check No. 150799 in the amount of $320.00 for submission of Appellants' Brief in support of an appeal; and
3. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-1824. A duplicate copy of this letter is enclosed.

Sincerely,

June E. Cohan (Reg. No. 43,741)
David R. Marsh (Reg. No. 41,408)

Enclosures